



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0319]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Dear Health Care Provider Letters: Improving Communication of Important Safety Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0754. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Dear Health Care Provider Letters: Improving Communication of Important Safety Information

OMB Control Number 0910-0754--Extension

This information collection supports recommendations found in the Agency guidance document entitled "Dear Health Care Provider Letters: Improving Communication of Important Safety Information." The guidance provides instruction to industry and FDA staff on the content and format of Dear Health Care Provider (DHCP) letters. These letters are sent by manufacturers or distributors to health care providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising. The guidance is available from our website at: <https://www.fda.gov/media/79793/download>.

The guidance document gives specific instruction on what should and should not be included in DHCP letters. Some DHCP letters have been too long, have contained promotional material, or otherwise have not met the goals set forth in the applicable regulation (21 CFR 200.5). In some cases, health care providers have not been aware of important new information, and have been unable to communicate it to patients, because the letters' content and length have made it difficult to find the relevant information. In addition, letters have sometimes been sent for the wrong reasons.

In addition to content and format recommendations for each type of DHCP letter, the guidance also includes recommendations on consulting with FDA on how to develop a DHCP

letter, when to send a letter, what type of letter to send, and how to assess the letter's impact. Based on a review of FDA's Document Archiving, Reporting, and Regulatory Tracking System for 2016--2018, we identified 38 DHCP letters that were sent by 24 distinct sponsors during the 3-year timeframe. We estimate that we will receive approximately 13 DHCP letters annually from approximately 8 application holders. FDA professionals familiar with DHCP letters, and with the recommendations in the guidance, estimate that it should take an application holder approximately 100 hours to prepare and send DHCP letters in accordance with the guidance.

In the *Federal Register* of August 19, 2019 (84 FR 42929), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received expressing the importance of communicating safety information, for which we are appreciative. No other comments were received.

We estimate the annual reporting burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Type of Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Dear Health Care Provider Letters	8	1.625	13	100	1,300

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection, we have reduced our burden estimate by 17 respondents with a corresponding decrease in annual hours by 1,200. We attribute the decrease to the effectiveness of the guidance.

Dated: November 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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